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APPELLANT'S BRIEF Address to: Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450	Application No.	10/029,408
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	First Named Inventor	CALDWELL, LARRY
	Examiner	VU, JAKE MINH
	Group Art	1618
	Title: " METHODS AND COMPOSITIONS FOR TREATING CARPAL TUNNEL SYNDROME"	

Sir:

This Brief is filed in support of the Appellants' appeal of the rejections set forth in the Office Action dated February 26, 2008. A Notice of Appeal was filed on July 25, 2008. In view of the enclosed petition for a 1-month extension of time, this Appeal Brief is timely filed.

The Board of Patent Appeals and Interferences has jurisdiction over this appeal pursuant to 35 U.S.C. § 134(a).

The Commissioner is hereby authorized to charge deposit account number 50-0815, order number CALD-005, to cover any required fee for filing the Appellant's brief. Additionally, in the event that the fee transmittal or other papers are separated from this document and/or other fees or relief are required, the Appellants petition for such relief, including extensions of time, and authorize the Commissioner to charge any fees under 37 C.F.R. §§ 1.16, 1.17 and 1.21 which may be required by this paper, or to credit any overpayment, to the above disclosed deposit account.

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REAL PARTY IN INTEREST

The real party in interest in this appeal is CALDWELL GALER, INC., as evidenced by the assignment recorded on April 16, 2002 at Reel/Frame: 012833 / 0882.

RELATED APPEALS AND INTERFERENCES

There are currently no other appeals or interferences known to the Appellants, the undersigned Appellants' representative, or the assignee to whom the inventor assigned his rights in the instant case, which would directly affect or be directly affected by, or have a bearing on the Board's decision in the instant appeal.

STATUS OF CLAIMS

The present application was filed December 26, 2001 with Claims 1 to 23. During the course of prosecution, the Appellants added new Claims 24-40, cancelled Claims 20-23, and amended Claims 1, 6, 11, 24 and 28. Accordingly, Claims 1-19 and 24-40 are pending in the present application, all of which stand rejected. As the claims have been twice rejected by the Office, the Appellants hereby appeal the case to the Board of Patent Appeals and Interferences pursuant to 35 U.S.C. § 134(a). All of the rejected claims are appealed herein.

STATUS OF AMENDMENTS

Subsequent to issuance of the Final Office Action dated February 26, 2008, no amendment was filed. As such, Claims 1-19 and 24-40 are presently pending.

SUMMARY OF CLAIMED SUBJECT MATTER

The rejected claims are drawn to methods including the step of topically applying an NSAID formulation to a palmar dermis of the subject proximal to the carpal tunnel, and kits for use in treating a subject suffering from pain associated with carpal tunnel syndrome. The subject methods ameliorate at least a symptom associated with pressure applied to the median nerve of the carpal tunnel of the host.

A description of each independent claim involved in the appeal and each dependent

claim argued separately is follows below.

Independent Claim 1 recites a method for at least ameliorating a symptom associated with pressure applied to the median nerve of the carpal tunnel of a host, comprising topically applying an effective amount of a topical NSAID formulation to a palmar dermal surface of said subject proximal to said carpal tunnel to ameliorate at least one symptom associated with pressure applied to the median nerve of the carpal tunnel of said host (page 3, lines 3-10).

Claim 4 recites the method according to Claim 1, wherein said topical formulation is a patch (page 3, line 8).

Independent Claim 6 recites a method of treating a mammal suffering from carpal tunnel syndrome (page 7, line 26 to page 8, line 1 and page 8, lines 7-8), comprising topically applying a nonsalicylate NSAID formulation to a palmar dermis of said mammal for a period of time sufficient for amelioration of at least one symptom of said syndrome to occur (page 3, lines 3-10) to treat said mammal (page 7, line 26 to page 8, line 1).

Independent Claim 11 recites a method for treating a human suffering from pain caused by pressure on the median nerve (page 3, lines 13-18), comprising topically applying a nonsalicylate NSAID formulation to the palmar dermis proximal to said median nerve in a manner sufficient to at least reduce said pain to treat said mammal (page 6, lines 15-25).

Claim 19 recites a kit for use in treating a subject suffering from pain associated with carpal tunnel syndrome, comprising a topical NSAID formulation and instructions for practicing the method according to Claim 1 (page 9, lines 1-17).

Independent Claim 24 recites a method for at least ameliorating a symptom associated with pressure applied to the median nerve of the carpal tunnel of a host (page 3, lines 3-10), comprising contacting a wrist band comprising a hydrogel patch comprising a topical NSAID formulation to a palmar dermal surface proximal to a carpal tunnel of a subject to topically apply an effective amount of said topical NSAID formulation to said palmar dermal surface proximal to said carpal tunnel to ameliorate at lest one symptom associated with pressure applied to the median nerve of the carpal tunnel of said host (page 8, lines 26-28 and page 9, line 23 to page 10, line 14).

Independent Claim 28 recites a method for treating a human suffering from pain caused by pressure on the median nerve (page 3, lines 13-18), comprising contacting a wrist band comprising a hydrogel patch comprising a nonsalicylate NSAID formulation to the palmar dermis proximal to said median nerve to topically apply said nonsalicylate NSAID formulation to said palmar dermis to treat said human (page 8, lines 26-28 and page 9, line 23 to page 10, line 14).

Claim 29 recites the method according to Claim 1, wherein said topical NSAID formulation comprises an NSAID in an amount ranging from about 0.1 to about 5% (page 8, line 25).

Claim 30 recites the method according to Claim 29, wherein said NSAID is diclofenac epolamine (page 9, line 23 to page 10, line 3).

Claim 31 recites the method according to Claim 30, wherein said topical NSAID formulation is a patch (page 9, line 23 to page 10, line 3).

Claim 32 recites the method according to Claim 31, wherein said patch comprises 1.3 % w/w of said NSAID (page 9, lines 23-28).

Claim 33 recites the method according to Claim 32, wherein said patch comprises a hydrogel adhesive present on a polyester felt backing (page 9, line 23 to page 10, line 3).

Independent Claim 34 recites a method for treating a subject for neuropathic symptoms associated with carpal tunnel syndrome (page 3, lines 3-10), comprising topically applying an effective amount of a topical NSAID formulation to a palmar dermal surface of said subject to treat said subject for neuropathic symptoms associated with carpal tunnel syndrome (page 3, lines 3-10).

Claim 35 recites the method according to Claim 1, wherein said at least one symptom ameliorated by said method is chosen from tingling, numbness and pain (page 7, lines 3-15).

Claim 36 recites the method according to Claim 35, wherein said host suffers from all of tingling, numbness and pain and said method ameliorates all of tingling, numbness and pain (page 9, lines 23-28).

Claim 37 recites the method according to Claim 35, wherein said topical NSAID formulation comprises from about 0.5 to 2% w/w of an active NSAID agent (page 6, lines 2-

7).

Claim 38 recites the method according to Claim 35, wherein said at least one symptom is ameliorated for a period of 1 week or longer following application of said topical NSAID formulation (page 7, lines 20-24).

Claim 39 recites the method according to Claim 38, wherein said at least one symptom is ameliorated for a period of several weeks or longer following application of said topical NSAID formulation (page 7, lines 20-24).

Claim 40 recites the method according to Claim 1, wherein said topical NSAID formulation comprises an NSAID as the only active agent (page 9, lines 23-28).

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

I. Claims 1-3, 5-8, 10-12, 14-18, 29, 34-36, 38 and 39 are rejected under 35 U.S.C. §103(a) as allegedly being obvious over Bockow (USPN 5,709,855) in view of Edwards (USPN 5,989,559).

II. Claims 4, 9 and 13 are rejected under 35 U.S.C. §103(a) as allegedly being obvious over Bockow (USPN 5,709,855) in view of Edwards (USPN 5,989,559) and Hirano (USPN 5,869,087).

III. Claim 19 is rejected under 35 U.S.C. §103(a) as allegedly being obvious over Bockow (USPN 5,709,855) in view of Edwards (USPN 5,989,559) and Shudo (US Pub No. 2002/0176886).

IV. Claims 24-28 are rejected under 35 U.S.C. §103(a) as allegedly being obvious over Bockow (USPN 5,709,855) in view of Edwards (USPN 5,989,559) and Hirano (U.S. Patent No. 5,869,087) and a bandage.

V. Claims 30-33, 37 and 40 are rejected under 35 U.S.C. §103(a) as allegedly being obvious over Bockow (USPN 5,709,855) in view of Edwards (USPN 5,989,559) and Liebschutz (PCT Pub WO 02/22109).

ARGUMENT

I. Claims 1-3, 5-8, 10-12, 14-18, 29, 34-36, 38 and 39 are not obvious under 35 U.S.C. §103(a) over Bockow (USPN 5,709,855) in view of Edwards (USPN 5,989,559).

In the arguments set forth below, Appellants will argue the rejected claims in groups as follows:

Group I: Claims 1-3, 5-8, 10-12, 14-18 and 35;
Group II: Claim 29;
Group III: Claim 34;
Group IV: Claim 36;
Group V: Claim 38; and
Group VI: Claim 39.

Group I: Claims 1-3, 5-8, 10-12, 14-18 and 35

Claims 1-3, 5-8, 10-12, 14-18 and 35 are drawn to methods including the step of topically applying an NSAID formulation to a palmar dermis of the subject proximal to the carpal tunnel. The methods ameliorate at least one symptom associated with pressure applied to the median nerve of the carpal tunnel of a host.

In making the rejection, the Examiner asserts that Bockow's use of a topical composition containing a cyclooxygenase inhibitor for treating pain (including the mention of treating pain from Carpal Tunnel Syndrome (CTS)), in combination with Edwards' treatment by applying a topical banana peel extract formulation to the wrist in Example P, renders the claims obvious.

The Appellants submit that, the claims of the pending application are patentable over the cited combination of references for at least the following reasons:

A. One of ordinary skill in the art would not have combined the teachings of the

cited references as asserted by the Office; and

B. One of ordinary skill in the art would not have predicted success in the claimed invention prior to the Appellants' work reported in the present application.

Each of these reasons for finding the asserted *prima facie* case of obviousness to be insufficient is further developed separately below.

A. No Apparent Reason to Combine References in Manner Suggested by the Office

The Appellants submit that there is no apparent and valid reason to combine the teachings of Bockow and Edwards, contrary to the position of the Office.

In *KSR*, "Courts determining whether claimed combination of elements known in prior art would have been obvious will often be required to look to interrelated teachings of multiple patents, effects of demands known to design community or present in marketplace, and background knowledge of person of ordinary skill in art in order to determine whether there was apparent reason to combine known elements in manner claimed in patent in suit, and in order to facilitate review, this analysis should be made explicit....." *KSR International v. Teleflex Inc.*, 127 S. Ct. 1727, 1739 (2007). As such, for a combination of elements to be obvious, there must be some apparent reason to combine the elements of the art in the manner stated in the claims at issue. Further, the background knowledge of a person of ordinary skill must be considered to determine the requisite apparent reason to combine the references.

In articulating a rationale to combine the prior art references, the Examiner states that, "The prior art teaches the methods for the topical administration of anti-inflammatory and/or analgesic agents for the treatment of CTS" (Final Office Action, page 8, ¶ 3). Further, in the Advisory Action, the Examiner asserts that, because Bockow explicitly discloses CTS, one skilled in the art would have viewed Bockow as teaching a method to treat CTS; and that, because both Bockow and Edwards deal with pain, there is apparent reason to combine the references.

Appellants submit that the Examiner's rational to combine the prior art references is based on incorrect assumption that CTS is a musculoskeletal disorder.

One of ordinary skill in the art reading Bockow would know that CTS is not a musculoskeletal disorder. Musculoskeletal disorders are entirely distinct from CTS, a type of neuropathy. This assertion by Appellants is based on the background knowledge in the art as evidenced by an article by Dieleman (Dieleman *et al.*, Incidence rates and treatment of neuropathic pain conditions in the general population, *Pain* 137:681–688 (31 July 2008)); and the declarations of record in the present application. The declarations are attached hereto in the Evidence Appendix.

First, CTS is not only a well-known neuropathy but also one of the most common neuropathies. The abstract of Dieleman states that CTS and mononeuropathy are the most frequent types of neuropathy. Further, on page 682, column 2, paragraph 2, Dielman describes in detail how CTS was selected as neuropathy by an expert committee comprising five neurologists and anesthesiologists. The passage is reproduced below.

> As GPs do not have an exhaustive coding system for the various types of neuropathic pain and nomenclature has changed over time, the cases of neuropathic pain were identified in four steps. First a small expert committee comprising five neurologists and anaesthesiologists selected the types of neuropathic pain to be included into the study. Second, a list of potential medical and lay names for the retrieval of potential cases of neuropathic pain from the free text in the electronic patient records was generated. This list was compiled by sending the list of selected types of neuropathic pain to a group of Dutch experts. Third, potential cases were identified in the database through an inclusive string search on free text and ICPC coded diagnoses. Finally, the presence and date of diagnosis of neuropathic pain were evaluated by a manual review of the electronic patient record of all the potential cases by medically trained persons. In order to minimize misclassification, we did not include the cases of mixed nociceptive and neuropathic pain. Our case definition relied on GP and specialist symptoms (e.g. shooting, burning pain, tingling, numbness) and diagnoses as recorded in the medical

record with the GP. GP diagnoses were accepted if they recurred in the patient record and if typical neuropathic pain symptoms were present. The index date was defined as the date of diagnosis of neuropathic pain.

The final list of the types of neuropathic pain selected by the expert committee comprised post-herpetic neuralgia, diabetic neuropathy, trigeminal neuralgia, glossopharyngeal neuralgia, atypical facial pain, mononeuropathy, hereditary and idiopathic neuropathy, post-surgical pain, traumatic nerve injury, carpal tunnel syndrome, cervical radiculopathy, phantom limb syndrome, spinal cord injury, syringomyela, spinal cord compression with metastases, multiple sclerosis and post-stroke pain. Among this selection, neuropathic pain sec-

Second, CTS and musculoskeletal disorders have entirely distinct pathologies. See Exhibit I attached hereto and the excerpt as follows:

> 3. In contrast to musculoskeletal disorders which are the target pathology in the Petrus reference, Carpal Tunnel Syndrome is not a species of musculoskeletal disorders. Rather, Carpal Tunnel Syndrome is a condition whose symptoms are caused by a disturbance of median nerve function in the wrist as the nerve passes through the carpal tunnel. As such, the pain and symptoms caused by Carpal Tunnel Syndrome do not arise from the musculoskeletal system. Instead, the pain, parasthesia, and dysesthesia arise from direct trauma and dysfunction to the median nerve within the carpal tunnel.

Third, because these two conditions arise from entirely distinct pathologies, those of ordinary skill in the art generally treat CTS and musculoskeletal disorders differently. See the declaration of Exhibit II attached hereto and the following excerpt:

6. Accordingly, in view of the difference in classification of musculoskeletal disorders and Carpal Tunnel Syndrome, those of skill in the art would approach the treatment of neuropathic pain conditions, of which Carpal Tunnel Syndrome is a member, differently from how they would approach the treatment of musculoskeletal pain disorders. In general, different classes of medications are prescribed for the treatment of neuropathic pain conditions as compared to the treatment of musculoskeletal pain disorders. See for example Exhibits C and D.

a. Exhibit C is an excerpt from an article entitled: Algorithm for Neuropathic Pain Treatment: An Evidence Based Proposal. The article sets forth a comparison of the various treatments used in the amelioration of neuropathic pains. Among the treatments used to remedy neuropathic pains are antidepressants (section 3.2) and anticonvulsants (section 3.3). See Finnerup, N. B. Pain 2005; 118:289-305 at page 290.

b. Exhibit D is an excerpt from the book entitled: Evidenced-Based Management of Acute Musculoskeletal Pain. The excerpt sets forth various treatments recommended for the management of acute musculoskeletal pains. The excerpt specifically points out that there is no evidence that supports the use of anti-depressants or anticonvulsants in the treatment of acute musculoskeletal pain. See page 22.

c. Accordingly, as can be seen with reference to Exhibits C and D, one of skill in the art would approach the treatment of a neuropathic pain differently from how they would approach the treatment of a musculoskeletal pain because in the treatment of a neuropathic pain one of skill in the art may recommend the administration of an anti-depressant or anticonvulsant where as for the treatment of a musculoskeletal pain one would not recommend the administration of an anti-depressant or anticonvulsant.

As shown above, the background knowledge of a person of ordinary skill is that CTS is a neuropathy, which is physiologically distinct from musculoskeletal disorders and is thus not a type of musculoskeletal disorders. Therefore, one of ordinary skill in the art would not read Bockow as teaching anything with respect to CTS.

Since the Examiner's asserted reason to combine Bockow with Edwards is based on Bockow's incorrect characterization of CTS, one of ordinary skill in the art would actually not combine the two references to use Bockow's formulation in Edward's method.

Accordingly, there is no apparent reason to combine Bockow with Edwards as has been done by the Examiner in making this rejection and this rejection may be reversed for this reason alone.

B. Predicted Success

The Appellants submit that one of ordinary skill in the art would not have predicted success in the claimed invention prior to the Appellants' work reported in the present application, as developed in greater detail below.

In determining whether a claimed invention is obvious, the Office must provide evidence that the combination would be "a predicted success". This principle is illustrated in *three* Supreme Court cases[1] decided prior to *KSR*, and is a recurring theme of *KSR*. For example, in *KSR*, the Supreme Court stated that in order for a combination of elements to be patentable, "the combination must do more than yield a predictable result".[2] Likewise, the corollary principle, namely that "The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results" is also discussed. [3] The Supreme Court in *KSR* also stated that "a court *must* ask whether the improvement is more than the predictable use of prior art elements according to their established functions".[4] Thus, according to the Supreme Court, an analysis of the "predictable success" of a combination of known elements may be used to separate patentable combinations (e.g., a battery that contains water, in the case of *United States* v. *Adams*, *supra*) from those that are unpatentable (e.g., an adjustable pedal having a fixed

1 *United States* v. *Adams*, 383 U.S. 39, 40 (1966); *Anderson's-Black Rock, Inc.* v. *Pavement Salvage Co.*, 396 U.C. 57, 60-62 (1969); and *Sakraida* v. *AG Pro, Inc.*, 425 U.C. 273, 282 (1976).
2 *KSR International v. Teleflex Inc.,* 127 S. Ct. 1727, 1740 (2007).
3 *KSR* at 1739.

pivot point and a sensor, in the case of *KSR, supra*).

The Examiner asserts that one of ordinary skill in the art has a reasonable expectation of success in applying the teachings of the Edwards patent to those of Bockow based on the finding that both patents deal with the treatment of pain and are thus analogous. See the sentence bridging pages 4 and 5 of the Non-Final Office Action dated July 17, 2007 (hereinafter the "Non-Final Office Action"), which is incorporated into the Final Office Action. Further, in the Advisory Action, the Examiner asserts that, because Bockow explicitly discloses the use of a pain-relieving composition for CTS, one skilled in the art would have a reasonable expectation of success.

However, as developed below, contrary to the Examiner's assertion, one of skill in the art would not have predicted success in the claimed methods – in particular, the effective delivery of an NSAID formulation to the median nerve inside the carpal tunnel and the subsequent treatment of CTS by the NSAID formulation.

First, one of ordinary skill in the art would not have predicted success in the effective delivery of an NSAID formulation to the median nerve inside the carpal tunnel upon topical application to a palmar dermis.

As described in the declaration of Exhibit III attached hereto and the following excerpt, an active agent for the treatment of CTS must cross tendons, blood vessels and especially a bone or a thickened sheath to reach the median nerve residing inside the carpal tunnel.

> In the subject methods, the active agent must cross a barrier to reach the target site to be effective. Barriers are present in the area of the carpal tunnel/median nerve. The carpal tunnel is the interior of the wrist through which the medial nerve, tendons and blood vessels pass. Three sides of the carpal tunnel are bone and the other side is a thickened sheath, the flexor retinaculum, which is made of ligament material. Accordingly, for the subject methods to work, the target agent must cross this bone/ sheath barrier.
>
> Furthermore, the active agent must penetrate deeply in order to reach a target site because

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4 *KSR* at 1740; emphasis added.

> carpal tunnel syndrome originates deep within the nerves of the wrist. Prior to my work in reducing the invention to practice, it was not at all certain that a sufficient amount of a given active agent would penetrate deeply enough to reach the target site.

Due to the above anatomical reasons, one of ordinary skill in the art would not predict success in delivering Bockow's composition to the median nerve inside the carpal tunnel without actually performing experiments and obtaining positive results. One of skill in the art must perform experiments and subsequently obtain positive results showing that an NSAID formulation, when applied to the palmar dermis, would cross tendons, blood vessels and especially a bone or a thickened sheath to reach the median nerve of the carpal tunnel. As such, without performing experiments, no skilled artisan could predict that an NSAID formulation would reach the median nerve within the carpal tunnel. As such, one of skill in the art could not have predicted success in delivering Bockow's composition to the median nerve inside the carpal tunnel.

Second, one of ordinary skill in the art would not have predicted success in treating CTS with an NSAID formulation, upon reading Bockow. As established above, one of ordinary skill in the art would not have read Bockow as teaching a composition for treating CTS, due to Bokow's incorrect characterization of CTS in light of the background knowledge. In addition, Bockow does not provide actual exemplification in the treatment of CTS.

Accordingly, one of skill in the art could not have predicted success in practicing the claimed invention prior to the Appellants' work reported in the present application because the elements of the prior art references would not perform the same function as they did separately.

In light of the above analysis, it is respectfully submitted that the Examiner's rejection is flawed because 1) there is no apparent reason to combine teachings of Bockow and Edwards as asserted by the Examiner based on the background knowledge in the art; and 2) one of skill in the art could not have predicted success in practicing the claimed invention by combining the elements of the prior art references in the manner that they

would perform the same function as they did separately. Consequently, the claims of Group I are not obvious under 35 U.S.C. §103(a) over Bockow in view of Edwards for many reasons and this rejection may be reversed.

Group II: Claim 29

Claim 29 is drawn to the method according to Claim 1 and thus includes all the elements of the claims of Group I. Therefore, Appellants submit that the claim of Group II is not obvious over Bockow in view of Edwards for the reasons detailed above for the claims of Group I.

The claim of Group II further includes an element that the topical NSAID formulation comprises an NSAID in an amount ranging from about 0.1 to about 5%.

Appellants submit that the claim of this group is further distinguished over Bockow in view of Edwards because the combination of the references fails to teach or suggest the claimed formulation containing an NSAID in an amount ranging from about 0.1 to about 5% for treating CTS.

The Examiner failed to provide a specific citation of Bockow or Edwards teaching a formulation containing an NSAID in an amount ranging from about 0.1 to about 5% for treating CTS.

Bockow teaches a topical composition containing a cyclooxygenase inhibitor, e.g., methyl salicylate, in an amount ranging from 3% to 25% by weight, which is much broader than the claimed range. Furthermore, formulations I to VI of Bockow's example I contain methyl salicylate in an amount ranging from 3% to 25% by weight (co. 7, lines 45 to col. 8, line 45). .Bockow's formulations containing methyl salicylate in an amount ranging from 3% to 25% are not shown to be effective in treating CTS. Rather, examples II and III of Bockow show that formulation II containing methyl salicylate was effective in relieving the

symptoms in patients with osteoarthritis, rheumatoid arthritis, tendinitis, bursitis, fibromyalgia, autoimmune disorders, chronic fatigue syndrome, sports-related injuries, tendinitis, bursitis, myositis, ligamentous or degenerative arthritis (col. 9, lines 20-55). None of these disorders are related to CTS in any way. As such, Bockow does not teach or suggest the claimed amount of an NSAID for treatment of CTS or any pain associated with neuropathy.

As Edwards is cited solely for its teachings of the application method, the reference fails to make up deficiencies in Bockow.

In light of the above, the Appellants submit that the combined teachings of the cited references fail to each and every element of Group II and thus do not render the claim of Group II obvious under 35 U.S.C. § 103. Accordingly, the reversal of this rejection is respectfully requested.

Group III: Claim 34

Claim 34 is drawn to a method for treating neuropathic symptoms associated with carpal tunnel syndrome and includes all the elements of the claims of Group I. Therefore, Appellants submit that the claim of Group III is not obvious over Bockow in view of Edwards for the reasons detailed above for the claims of Group I.

Claim 34 specifies that a subject for neuropathic symptoms is treated by the claimed method. As such, an element of the claim of Group III is the use of a topical NSAID formulation for the treatment of neuropathic symptoms.

Appellants submit that the combination of the cited references fails to teach or suggest this element of Group III and thus the claim group is further distinguished over Bockow in view of Edwards.

The Examiner does not cite any passage of Bockow or Edwards for this element.

Bockow is directed to a composition for the treatment of musculoskeletal disorders. There is no mention of the use of the composition for the treatment of neuropathic symptoms associated with a neuropathy condition.

As Edwards is cited solely for its teachings of the application method, the reference fails to make up deficiencies in Bockow.

Accordingly, the cited combination does not render the claim of Group III obvious under 35 U.S.C. § 103. Accordingly, the reversal of this rejection is respectfully requested.

Group IV: Claim 36

Claim 36 is drawn to the method according to Claim 35, which depends on Claim 1, and thus includes all the elements of the claims of Group I. Therefore, Appellants submit that the claim of Group IV is not obvious over Bockow in view of Edwards for the reasons detailed above for the claims of Group I.

Claim 36 further specifies that the host suffers from all of tingling, numbness and pain and the method ameliorates all of tingling, numbness and pain. As such, an element of Group IV is the use of a topical NSAID formulation for the amelioration of all of tingling, numbness and pain.

Appellants submit that the combination of the cited references fails to teach or suggest this element of Group IV and thus the claim is further distinguished over Bockow in view of Edwards.

As for this element, the Examiner asserts that the element is considered to be implicitly met by the teachings of the prior art because one of ordinary skill in the art would be aware of the symptoms of CTS (Final Office Action, page 4, last ¶).

Appellants note that in order to show that a prior art reference inherently teaches a particular element of the claim, the Examiner must provide evidence that the element necessarily flows from the teachings of the prior art reference.

The law is clear on this point. "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original). Furthermore, the fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993).

Bockow, the reference cited by the Examiner for teaching an NSAID formulation, lists symptoms that are ameliorated by its formulation but none of the symptoms include all of all of tingling, numbness and pain. Indeed, since Bockow's formulation is directed to treating musculoskeletal disorders, the formulation is likely to ameliorate the symptoms associated with musculoskeletal disorders not the symptoms associated with the neuropathy CTS. As such, Bockow's NSAID formulation does not necessarily ameliorate all of tingling, numbness and pain. Bockow fails to teach or suggest the element of this group.

As Edwards is cited solely for its teachings of the application method, the reference fails to make up deficiencies in Bockow.

Lastly, contrary to the Examiner's assertion, amelioration of all tingling, numbness and pain in treating CTS does not necessarily flow from the background knowledge of one of ordinary skill in the art. Edwards, the reference directed to treating CTS by banana peel extracts, does not teach ameliorating all of tingling, numbness and pain in a patient with

CTS (see example P). This shows that ameliorating all of tingling, numbness and pain in a patient with CTS cannot be considered to necessarily flow from the background knowledge of one of skill in the art, as evidenced by Edwards.

In light of above, the Appellants submit that the cited references additionally fail to teach or suggest a claimed element of Group III and thus do not render the claim of Group III obvious under 35 U.S.C. § 103. Accordingly, the reversal of this rejection is respectfully requested.

Group V: Claim 38

Claim 38 is drawn to the method according to Claim 35, which depends on Claim 1, and thus includes all the elements of the claims of Group I. Therefore, Appellants submit that the claim of Group V is not obvious over Bockow in view of Edwards for the reasons detailed above for the claims of Group I.

Claim 38 further specifies that at least one symptom selected from tingling, numbness and pain is ameliorated for a period of 1 week or longer following application of the topical NSAID formulation. As such, an element of Group V is amelioration of a symptom for a period of 1 week or longer following application of a topical formulation.

Appellants submit that the combination of the cited references fails to teach or suggest this element of Group V because neither Bockow nor Edwards teach or suggest this element and the Examiner did not provide a basis that reasonably supports the determination that, upon the treatment, the symptoms of CTS are necessarily ameliorated for a period of 1 week or longer.

As for this claim, the Examiner states that this element is expected upon successful treatment of CTS and is thus implicitly met by the teachings of the prior art. Final Office Action, ¶ bridging pgs 4 and 5.

As described for the claim of Group IV, in relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art. However, the Examiner did not provide any reasoning except his conclusion that the claimed elements are inherent upon successful treatment of CTS. Indeed, Bockow indicates that the amelioration of the symptoms of a musculoskeletal disorder lasts only up to 24 hours because it teaches application of its formulations 1-4 times daily (col. 7, lines 15-24). As such, Bockow does not teach or suggest the claimed element that the amelioration lasts for at least 1 week.

As Edwards is cited solely for its teachings of the application method, the reference fails to make up deficiencies in Bockow. Further, Edwards is silent on how long amelioration lasts following application of its banana peel extracts.

In light of the above, the Appellants submit that the combination of cited references additionally fail to teach or suggest a claimed element of Group V and thus does not render the claim of Group V obvious under 35 U.S.C. § 103. Accordingly, the reversal of this rejection is respectfully requested.

Group VI: Claim 39

Claim 39 is drawn to the method according to Claim 38, and thus includes all the elements of the claims of Groups I and V. Therefore, Appellants submit that the claim of Group VI is not obvious over Bockow in view of Edwards for the reasons detailed above for the claims of Groups I and V.

Claim 39 further specifies that the amelioration lasts for a period of several weeks or longer.

Appellants submit that the combination of the combination of cited references fails to teach or suggest the element of Group V because the Examiner did not provide a basis

that reasonably supports the determination that, upon the treatment, the symptoms of CTS are necessarily ameliorated for a period of several weeks or longer.

As for this claim, the Examiner states that the element is expected upon successful treatment of CTS and is thus implicitly met by the teachings of the prior art. Final Office Action, ¶ bridging pgs 4 and 5.

As described for the claim of Group V, in relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.

Amelioration for a period of several weeks or longer following application of a topical formulation is a surprising finding. Such a surprising finding does not necessarily flow from the teachings of the prior art, especially when the prior art indicates its compositions is effective only with respect non-CTS conditions up to 24 hours. The Examiner did not provide any reasoning except his conclusion that the claimed elements are inherent upon successful treatment of CTS.

As Edwards is cited solely for its teachings of the application method, the reference fails to make up deficiencies in Bockow. Further, Edwards is silent on how long amelioration lasts following application of its banana peel extracts.

Accordingly, the Appellants submit that the combination of cited references additionally fail to teach or suggest a claimed element of Group VI because the Examiner did not provide any basis as to its determination that the claimed elements would be necessarily present in the prior art. Accordingly, the reversal of this rejection is respectfully requested.

II. Claims 4, 9, and 13 are not obvious under 35 U.S.C. §103(a) over Bockow (USPN

5,709,855) in view of Edwards (USPN 5,989,559) and Hirano (USPN 5,869,087).

In the arguments set forth below, the Appellants will argue the rejected claims in a single group.

Claims 4, 9 and 13 are drawn to methods for at least ameliorating a symptom associated with pressure applied to the median nerve of the carpal tunnel by topically applying an NSAID formulation, where the topical formulation is a patch.

In making this rejection, the Examiner asserts that Bockow in view of Edwards teach all of the elements of the claims but for the topical patch, and that element is made up by Hirano.

Claims 4, 9 and 13 include all of the elements of the claims of Group I, which are topically applying an NSAID formulation to a palmar dermis of the subject proximal to the carpal tunnel to ameliorate at least one symptom associated with pressure applied to the median nerve of the carpal tunnel.

As such, Appellants submit that Claims 4, 9 and 13 are not obvious over Bockow in view of Edwards because 1) there is no apparent reason to combine teachings of Bockow and Edwards as asserted by the Examiner based on the background knowledge in the art; and 2) one of skill in the art could not have predicted success in practicing the claimed invention by combining the elements of the prior art references in the manner that they would perform the same function as they did separately, as detailed above for the claims of Group I.

As Hirano was cited solely for the patch element, Hirano fails to make up this deficiency in the primary references and this rejection may be reversed.

III. Claim 19 is not obvious under 35 U.S.C. §103(a) over Bockow (USPN 5,709,855) in

view of Edwards (USPN 5,989,559) and Shudo (US Pub No. 2002/0176886).

Claim 19 is drawn to a kit for use in treating a subject suffering from pain associated with carpal tunnel syndrome. The kit includes a topical NSAID formulation and instructions for practicing the method according to Claim 1.

In making this rejection, the Examiner asserts that Bockow in view of Edwards teach all of the elements of the claimed invention but for the kit comprising topical patch formulations and instructions for use, and that element is made up by Shudo.

Claim 19 includes all the elements of the claims of Group I, which are topically applying an NSAID formulation to a palmar dermis of the subject proximal to the carpal tunnel to ameliorate at least one symptom associated with pressure applied to the median nerve of the carpal tunnel.

As such, Appellants submit that Claim 19 is not obvious over Bockow in view of Edwards because 1) there is no apparent reason to combine teachings of Bockow and Edwards as asserted by the Examiner based on the background knowledge in the art; and 2) one of skill in the art could not have predicted success in practicing the claimed invention by combining the elements of the prior art references in the manner that they would perform the same function as they did separately, as detailed above for the claims of Group I.

As Shudo was cited solely for the kit element, Shudo fails to make up this deficiency in the primary references and this rejection may be reversed.

IV. Claims 24-28 are not obvious under 35 U.S.C. §103(a) over Bockow (USPN 5,709,855) in view of Edwards (USPN 5,989,559) and Hirano (U.S. Patent No. 5,869,087) and a bandage

In the arguments set forth below, the Appellants will argue the rejected claims in a single group.

Claims 24-28 are drawn to methods including the step of contacting a wrist band comprising a hydrogel patch comprising a topical NSAID formulation to a palmar dermal surface proximal to a carpal tunnel of a subject to topically apply an effective amount of the topical NSAID formulation to the palmar dermal surface proximal to the carpal tunnel. The methods ameliorate at least one symptom associated with pressure applied to the median nerve of the carpal tunnel of the host.

In making this rejection, the Examiner asserts that Bockow in view of Edwards teach all of the elements of the claims but for the topical patch, and that element is made up by Hirano.

Claims 24-28 include all the elements of the claims of Group I, which are topically applying an NSAID formulation to a palmar dermis of the subject proximal to the carpal tunnel to ameliorate at least one symptom associated with pressure applied to the median nerve of the carpal tunnel.

As such, Appellants submit that Claims 24-28 are not obvious over Bockow in view of Edwards because 1) there is no apparent reason to combine teachings of Bockow and Edwards as asserted by the Examiner based on the background knowledge in the art; and 2) one of skill in the art could not have predicted success in practicing the claimed invention by combining the elements of the prior art references in the manner that they would perform the same function as they did separately, as detailed above for the claims of Group I.

As Hirano was cited solely for the patch element, Hirano fails to make up this deficiency in the primary references and this rejection may be reversed.

V. Claims 30-33, 37 and 40 are not obvious under 35 U.S.C. §103(a) over Bockow (USPN 5,709,855) in view of Edwards (USPN 5,989,559) and Liebschutz (PCT Pub WO 02/22109).

In the arguments set forth below, the Appellants will argue the rejected claims in groups as follows:

Group VII: Claims 30 and 31;
Group VIII: Claims 37;
Group IX: Claims 32;
Group X: Claim 33; and
Group XI: Claim 40.

Group VII: Claims 30 and 31

Claims 30 and 31 are drawn to methods according to Claim 29, which specifies that the NSAID formulation comprises an NSAID in an amount ranging from about 0.1 to about 5%.

In making this rejection, the Examiner asserts that Bockow in view of Edwards teach all of the elements of the claims but for the use of diclofenac epolamine in the form of a patch, and that element is made up by Liebschutz.

Claims 30 and 31 include all the elements of the claims of Group I, which are topically applying an NSAID formulation to a palmar dermis of the subject proximal to the carpal tunnel to ameliorate at least one symptom associated with pressure applied to the median nerve of the carpal tunnel. As such, Appellants submit that Claims 30 and 31 are not obvious over Bockow in view of Edwards because 1) there is no apparent reason to combine teachings of Bockow and Edwards as asserted by the Examiner based on the background knowledge in the art; and 2) one of skill in the art could not have predicted success in practicing the claimed invention by combining the elements of the prior art

references in the manner that they would perform the same function as they did separately, as detailed above for the claims of Group I.

As Liebschutz was cited solely for the use of diclofenac epolamine in the form of a patch and is completely silent on the use for treatment of CTS, Liebschutz fails to make up this deficiency in the primary references and this rejection may be reversed.

Group VIII: Claim 37

Claims 37 is drawn to the method according to Claim 35 (which depends on Claim 1), where the topical NSAID formulation comprises 0.5 to 2% w/w of an active NSAID. As such, the claim of Group VIII includes all the elements of the claims of Group I. Therefore, Appellants submit that the claim of Group VIII is not obvious over Bockow in view of Edwards and Liebschutz for the reasons detailed above for the claims of Group VII.

The claim of Group VIII further includes an element that the topical NSAID formulation comprises about 0.5 to 2% w/w of an active NSAID.

For this element, the Examiner cites to page 3, section (b)(1) of Liebschutz, which teaches a topical patch containing diclofenac epolamine in the preferred amount of 1% to 5% of the matrix layer. See Non-Final Office Action, page 14, ¶ 2.

Appellants submit that the claim of this group is further distinguished over Bockow in view of Edwards and Liebschutz because the combination of the cited references fails to teach or suggest the topical NSAID formulation comprising about 0.5 to 2% w/w of an active NSAID, as claimed.

Liebschutz provides three examples in which the patches all contain 2.5-3% of diclofenac, which is outside the claimed range of about 0.5 to 2% w/w. The Examiner does not present any reasoning as to why the skilled artisan would choose an amount of diclofenac in a range much below 2.5% when all patches of the examples in Liebschutz

contain 2.5% or higher diclofenac.

Furthermore, Bockow teaches away from a topical formulation containing 0.5 to 2% of NSAID because all it teaches is topical formulations containing 3-25% of NSAID. As such, upon reading Liebschutz and Bockow, one of skill in the art would be motivated to include at least 3% of NSAID in producing a topical NSAID formulation.

As Edwards is cited solely for its teachings of the application method, the reference fails to make up deficiencies in Bockow and Liebschutz.

In light of the above, the Appellants submit that the combination of the cited references fails to teach or suggest every element of Claim 37, and thus the claim is not obvious under 35 U.S.C. § 103. Accordingly, the reversal of this rejection is respectfully requested.

Group IX: Claim 32

Claim 32 is drawn to the method according to Claim 31, where the patch comprises 1.3% w/w of the NSAID. As such, the claim of Group IX includes all the elements of Claim 31 of Group VII and the element of Group VIII, which is a topical NSAID formulation comprising about 0.5 to 2% w/w of an active NSAID. Therefore, Appellants submit that the claim of Group IX is not obvious over Bockow in view of Edwards and Liebschutz for the reasons detailed above for the claims of Group VII and VIII, respectively.

The claim of Group IX further includes an element of 1.3% w/w of an active NSAID.

For this element, the Examiner cites to page 3, section (b)(1) of Liebschutz, which teaches a topical patch containing diclofenac epolamine in the preferred amount of 1% to 5% of the matrix layer. See Non-Final Office Action, page 14, ¶ 2.

Appellants submit that the claim of this group is further distinguished over Bockow in view of Edwards and Liebschutz because the claimed 1.3% w/w of an active NSAID is not taught or suggested by the combination of the references. 1.3% w/w of an active NSAID refers to a very specific amount of the NSAID. Nowhere does Liebschutz mention this specific amount of the NSAID. Moreover, as explained for Group VIII, all the examples of Liebschutz provide patches containing 2.5-3% of diclofenac, which is at least twice that of the claimed amount. On the other hand, Bockow teaches topical formulations all containing 3-25% of NSAID, which is also more than twice that of the claimed amount. As such, Bockow does not teach or suggest the claimed amount.

For this reason, Bockow and Liebschutz cannot be combined because the two references teach different amounts of an NSAID in a topical formulation. Furthermore, there is no guidance for one of skill in the art to select 1.3% w/w of an active NSAID between the conflicting teachings of the references. Therefore, Appellants submit that the combination of Bockow and Liebschutz does not teach or suggest the claimed 1.3% w/w of an active NSAID.

As Edwards is cited solely for the application method, Edwards does not make up the deficiencies of Bockow and Liebschutz.

In light of the above, the Appellants submit that the combination of the references additionally fails to teach each and every element of Claim 32, and thus the claims is not obvious under 35 U.S.C. § 103. Accordingly, the reversal of this rejection is respectfully requested.

Group X: Claim 33

Claim 33 is drawn to the method according to Claim 32, where said patch comprises a hydrogel adhesive present on a polyester felt backing. As such, the claim of Group X includes 1) all the elements of Claim 31, base claim of Claim 32, of Group VII; 2) the elements of Claim 32 of Group IX; and 3) the element of Group VIII, which includes the

elements of Claim 32. Therefore, Appellants submit that the claim of Group IX is not obvious over Bockow in view of Edwards and Liebschutz for the reasons detailed above for the claims of Groups VII, VIII and IX, respectively.

Claim 33 of Group X further includes two elements: 1) a hydrogel adhesive and 2) a polyester felt backing.

Appellants submit that the combination of the references fails to teach or suggest each and every element of the rejected claim – e.g., a hydrogel adhesive and a polyester felt backing.

The Examiner cites Liebschutz for the teaching of a patch in general, but fails to cite a specific passage of the reference for these elements.

The patch disclosed in Liebschutz includes a matrix layer having pressure sensitive adhesive properties (page 3, ¶ 4). However, the reference fails to specify a type of materials for the adhesive. As such, the reference fails to teach or suggest a hydrogel adhesive as recited in the claim.

Furthermore, Liebschutz's patch employs an impermeable backing layer (page 2, ¶ 3). The reference teaches ethylene/vinyl acetate copolymer or polyolefin foams as materials for the impermeable backing layer (page 3, ¶ 3). Ethylene/vinyl acetate copolymer or polyolefin foams are entirely different from polyester felt, as required in the claim. As such, the reference also fails to teach or suggest a polyester felt backing.

As Liebschutz is cited solely for its teaching of a patch, Bockow in view of Edwards fails to make up deficiencies in Liebschutz.

In light of the above, the Appellants submit that the combination of cited references additionally fails to teach or suggest at least two claimed elements of Group X and thus

does not render the claim of Group X obvious under 35 U.S.C. § 103. Accordingly, the reversal of this rejection is respectfully requested.

Group XI: Claim 40

Claim 40 is drawn to the method according to Claim 1, where the topical NSAID formulation comprises an NSAID as the only active agent. As such, the claim of Group XI includes all the elements of Group VII. Therefore, Appellants submit that the claim of Group XI is not obvious over Bockow in view of Edwards and Liebschutz for the reasons detailed above for the claims of Group VII.

Claim 40 of Group XI further includes an element that the NSAID is the only active agent of the topical NSAID formulation.

In making this rejection, it appears that the Examiner attempts to eliminate the omega fatty acid and spirulina from Bockow's formulation, alleging that Liebschutz teaches a patch containing diclofenac as the only active agent. By combining the teachings of Bockow and Liebschutz, the Examiner modifies Bockow's formulation so that an NSAID becomes the only active agent as recited in Claim 40.

Appellants submit that the combination of the references fails to teach or suggest this element because Bockow teaches away from topical NSAID formulations comprising an NSAID as the only active agent and would be rendered unsatisfactory for its intended purpose if modified as proposed by the Examiner.

Bockow teaches away from a topical formulation comprising an NSAID as the <u>only</u> active agent because Bockow's formulation <u>requires</u> the presence of an omega fatty acid and spirulina, both as active agents. As shown in the abstract below, Bockow teaches that the inclusion of a cyclooxygenase inhibitor, e.g., NSAIDs, is optional.

> The composition contains an omega fatty acid in combination with spirulina. Preferably, the omega fatty acid is a mixture of omega-3 fatty acids and omega-6

> fatty acids. Omega-3 fatty acids include eicosapentaenoic acid and docosahexanoic acid, and omega-6 fatty acids include gamma-linolenic acid and dihomo-gamma-linolenic acid. The composition may further include pharmaceutically acceptable carriers or diluents, vitamins A and E, and a cyclooxygenase inhibitor such as methyl salicylate.

A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied,* 469 U.S. 851 (1984). Bokow, when considered in its entirety, clearly teaches formulations that require omega and spirulina, and therefore, when looked at as a whole, Bokow teaches away from a formulation that includes NSAID as the only active agent.

Furthermore, the inclusion of an omega fatty acid and spirulina in its formulation is central to Bockow. Per Bockow, an omega fatty acid is a known inhibitor of inflammation (col. 1, lines 65-67) and spirulina is known for providing numerous health benefits (col. 4, line 61 to col. 5, line 14). Since the inclusion of an omega fatty acid and spirulina is key to the success of Bockow's formulation, the omega fatty acid and spirulina cannot be eliminated from its formulation without rendering Bockow inoperable and unsuitable for its intended purpose. As such, the proposed modification would render Bockow unsatisfactory for its intended purpose. If a proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). Thus, Bockow provides no suggestion or motivation to make the modification proposed by the Examiner.

Consequently, Claim 40 is additionally distinguished over Bockow in view of Liebschutz. Accordingly, the rejection of Claim 40 should be reversed.

In Summary, Appellants submit that:

I. Claims 1-3, 5-8, 10-12, 14-18, 29, 34-36, 38 and 39 are not obvious under 35 U.S.C. §103(a) over Bockow (USPN 5,709,855) in view of Edwards (USPN 5,989,559) because 1) there is no apparent reason to combine teachings of Bockow and Edwards as asserted by the Examiner based on the background knowledge in the art; and 2) one of skill in the art could not have predicted success in practicing the claimed invention by combining the elements of the prior art references in the manner that they would perform the same function as they did separately;

II. Claims 4, 9, and 13 are not obvious under 35 U.S.C. §103(a) over Bockow (USPN 5,709,855) in view of Edwards (USPN 5,989,559) and Hirano (USPN 5,869,087);

III. Claim 19 is not obvious under 35 U.S.C. §103(a) over Bockow (USPN 5,709,855) in view of Edwards (USPN 5,989,559) and Shudo (US Pub No. 2002/0176886);

IV. Claims 24-28 are not obvious under 35 U.S.C. §103(a) over Bockow (USPN 5,709,855) in view of Edwards (USPN 5,989,559) and Hirano (U.S. Patent No. 5,869,087) and a bandage; and

V. Claims 30-33, 37 and 40 are not obvious under 35 U.S.C. §103(a) over Bockow (USPN 5,709,855) in view of Edwards (USPN 5,989,559) and Liebschutz (PCT Pub WO 02/22109).

In light of the above arguments, the Appellants respectfully request that all rejections of Claims 1-19 and 24-40 be reversed and that the application be remanded to the Examiner with instructions to issue a Notice of Allowance.

Respectfully submitted,

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CLAIMS APPENDIX

1. A method for at least ameliorating a symptom associated with pressure applied to the median nerve of the carpal tunnel of a host, said method comprising:

topically applying an effective amount of a topical NSAID formulation to a palmar dermal surface of said subject proximal to said carpal tunnel;

to ameliorate at least one symptom associated with pressure applied to the median nerve of the carpal tunnel of said host.

2. The method according to Claim 1, wherein said topical NSAID formulation comprises a nonsalicylate NSAID.

3. The method according to Claim 1, wherein said topical formulation is a cream.

4. The method according to Claim 1, wherein said topical formulation is a patch.

5. The method according to Claim 1, wherein said host is a mammal.

6. A method of treating a mammal suffering from carpal tunnel syndrome, said method comprising:

topically applying a nonsalicylate NSAID formulation to a palmar dermis of said mammal for a period of time sufficient for amelioration of at least one symptom of said syndrome to occur;

to treat said mammal.

7. The method according to Claim 6, wherein said mammal is a human.

8. The method according to Claim 6, wherein said formulation is a cream.

9. The method according to Claim 6, wherein said formulation is a patch.

10. The method according to Claim 6, wherein said symptom is pain.

11. A method for treating a human suffering from pain caused by pressure on the median nerve, said method comprising:

topically applying a nonsalicylate NSAID formulation to the palmar dermis proximal to said median nerve in a manner sufficient to at least reduce said pain;

to treat said mammal.

12. The method according to Claim 11, wherein said NSAID formulation is a cream.

13. The method according to Claim 11, wherein said NSAID formulation is a patch.

14. The method according to Claim 11, wherein said NSAID is an acetic acid.

15. The method according to Claim 14, wherein said NSAID is diclofenac.

16. The method according to Claim 11, wherein said NSAID is indomethacin.

17. The method according to Claim 11, wherein said NSAID is ibuprofen.

18. The method according to Claim 11, wherein said NSAID is ketoprofen.

19. A kit for use in treating a subject suffering from pain associated with carpal tunnel syndrome, said kit comprising:

a topical NSAID formulation; and

instructions for practicing the method according to Claim 1.

24. A method for at least ameliorating a symptom associated with pressure applied to the median nerve of the carpal tunnel of a host, said method comprising:

contacting a wrist band comprising a hydrogel patch comprising a topical NSAID formulation to a palmar dermal surface proximal to a carpal tunnel of a subject to topically apply an effective amount of said topical NSAID formulation to said palmar dermal surface proximal to said carpal tunnel;

to ameliorate at lest one symptom associated with pressure applied to the median nerve of the carpal tunnel of said host.

25. The method according to Claim 24, further comprising holding said patch in place relative to said palmar dermal surface for a period of time.

26. The method according to Claim 25, wherein said period of time is at least about 30 minutes.

27. The method according to Claim 24, wherein said NSAID formulation is at least one of: acetic acid, diclofenac, indomethacin, ibuprofen, and ketoprofen.

28. A method for treating a human suffering from pain caused by pressure on the median nerve, said method comprising:

contacting a wrist band comprising a hydrogel patch comprising a nonsalicylate NSAID formulation to the palmar dermis proximal to said median nerve to topically apply said nonsalicylate NSAID formulation to said palmar dermis;

to treat said human.

29. The method according to Claim 1, wherein said topical NSAID formulation comprises an NSAID in an amount ranging from about 0.1 to about 5%.

30. The method according to Claim 29, wherein said NSAID is diclofenac epolamine.

31. The method according to Claim 30, wherein said topical NSAID formulation is a patch.

32. The method according to Claim 31, wherein said patch comprises 1.3 % w/w of said NSAID.

33. The method according to Claim 32, wherein said patch comprises a hydrogel adhesive present on a polyester felt backing.

34. A method for treating a subject for neuropathic symptoms associated with carpal tunnel syndrome, said method comprising:

topically applying an effective amount of a topical NSAID formulation to a palmar dermal surface of said subject;

to treat said subject for neuropathic symptoms associated with carpal tunnel syndrome.

35. The method according to Claim 1, wherein said at least one symptom ameliorated by said method is chosen from tingling, numbness and pain.

36. The method according to Claim 35, wherein said host suffers from all of tingling, numbness and pain and said method ameliorates all of tingling, numbness and pain.

37. The method according to Claim 35, wherein said topical NSAID formulation comprises from about 0.5 to 2% w/w of an active NSAID agent.

38. The method according to Claim 35, wherein said at least one symptom is

ameliorated for a period of 1 week or longer following application of said topical NSAID formulation.

39. The method according to Claim 38, wherein said at least one symptom is ameliorated for a period of several weeks or longer following application of said topical NSAID formulation.

40. The method according to Claim 1, wherein said topical NSAID formulations comprises an NSAID as the only active agent.

Evidence Appendix

A copy of the following Declarations are provided in this Appendex:

- the Declaration by Bradley Galer under 37 CFR § 1.132 and accompanying exhibits filed on May 9, 2007 as Exhibit I;
- the Declaration by Bradley Galer under 37 CFR § 1.132, his *curriculum vitae* and accompanying exhibits filed on June 5, 2006 as Exhibit II; and
- the Declaration by Larry Caldwell under 37 CFR § 1.132 and his *curriculum vitae* filed on April 26, 2005 as Exhibit III.

Related Proceedings Appendix

As stated in the *Related Appeals and Interferences* section above, there are no other appeals or interferences known to Appellants, the undersigned Appellants' representative, or the assignee to whom the inventors assigned their rights in the instant case, which would directly affect or be directly affected by, or have a bearing on the Board's decision in the instant appeal. As such this section is left blank.